

PTO/SB/08a (05-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

perwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number		10036129		
Filing Date		2001-12-26		
First Named Inventor Tane		ja, Rajneesh		
Art Unit		1615		
Examiner Name	Hume	era N. Sheikh		
Attorney Docket Number		065478-0298		

				U.S.	PATENTS	
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4554276		2007-10-17	LaMattina	
	2	4676984		1987-06-30	Wu et al.	
	3	4757060		1988-07-12	Lukacsko et al.	
	4	4766117		1988-08-23	Crawford et al.	
	5	4853230		1988-11-22	Lovgren et al.	
	6	5037815		1991-08-06	Lukacsko et al.	
	7	5071643		1991-12-10	Yu et al.	
	8	5204118		1993-04-20	Goldman et al.	

Application Number	10036129
Filing Date	2001-12-26
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	Humera N. Sheikh
Attorney Docket Numb	er 065478-0298

			 		· · · · · · · · · · · · · · · · · · ·
	9	5417980	1995-05-23	Goldman et al.	
į.	10	5629013	1997-05-13	Upson et al.	
	11	5753265	1998-05-19	Bergstrand et al.	
	12	5763422	1998-06-09	Lichtenberger et al.	
	13	5817338	1998-10-06	Bergstrand et al.	
	14	5955451	1999-09-21	Lichtenberger et al.	
	15	5972389	1999-10-26	Shell et al.	
	16	6015801	2000-01-18	Daifotis et al.	
	17	6024222	2000-02-15	Friberg et al.	
	18	6090827	2000-07-18	Erickson et al.	
	19	6160020	2000-12-12	Ohannesian et al.	

Application Number		10036129				
Filing Date		2001-12-26				
First Named Inventor	Tane	ja, Rajneesh				
Art Unit	· · · · · ·	1615				
Examiner Name	Hume	era N. Sheikh				
Attorney Docket Number		065478-0298				

20	6183779	2001-02-06	Ouali et al.	
21	6365184	2002-04-02	Depui et al.	
22	6392525	2002-05-21	Kato et al.	
23	6544556	2003-04-08	Chen et al.	·
24	6613354	2003-09-02	Depui et al.	
25	6759935	2004-07-06	Moro et al.	
 26	4786505	1998-11-22	Lovgren et al.	·
27	5464632	1995-11-07	Cousin et al.	
28	5731002	1998-03-24	Olovson et al.	
29	6299904	2001-10-09	Shimizu et al.	
30	6328994	2001-12-11	Shimizu et al.	

( Not for submission under 37 CFR 1.99)

Application Number		10036129	
Filing Date		2001-12-26	
First Named Inventor	Tane	ja, Rajneesh	
Art Unit		1615	
Examiner Name	Hum	era N. Sheikh	
Attorney Docket Number		065478-0298	

					· · · · · · · · · · · · · · · · · · ·	
	31	6489346		2002-12-02	Phillips et al.	
	32	6183776		2001-02-06	Depui et al.	
	33	5589491		1996-12-31	Nakanishi et al.	
	34	5750104		1998-05-12	Sipos	
	35	6328993		2001-12-11	Linder et al.	
	36	5312818		1994-05-17	Rubin et al.	
	37	6013281		2000-01-11	Lundberg	
	38	6258845		2001-07-01	Gerner	
	39	5952021		1999-09-14	Santus	
	40	6800307		2004-10-05	Matthews et al.	
If you wish	to ad	d additional U.S. Paten	t citatio	n information pl	ease click the Add button.	

**U.S.PATENT APPLICATION PUBLICATIONS** 

PTO/SB/08a (05-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	Application Number		10036129	
INFORMATION DISCLOSURE	Filing Date First Named Inventor		2001-12-26 ja, Rajneesh	
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit		1615	
(Not for Submission under or or it issue	Examiner Name		era N. Sheikh	
	Attorney Docket Numb	er	065478-0298	

					U.S.I	PATENTS				
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>			Name of Patentee or Applicant of cited Document		Pages,Columns,Lines where Relevant Passages or Relev Figures Appear		
	1									
If you wis	h to ac	l dd additional U.S. Pater	nt citatio	n inform	ation pl	ease click the	Add button.			
			U.S.P	ATENT	APPLIC	CATION PUBL	LICATIONS		· · · · · · · · · · · · · · · · · · ·	
Examiner Initial*	Publication Number			tion	of cited Document			s,Columns,Lines where vant Passages or Releves es Appear		
	1									
If you wis	h to ac	ı dd additional U.S. Publi	shed Ap	plication	citation	n information p	lease click the Add	d butto	on.	
				FOREIG	SN PAT	ENT DOCUM	ENTS			
Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>		Kind Code <sup>4</sup>	Publication Date	Name of Patented Applicant of cited Document		Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	75
	1	58056664	JP			1983-04-04				
	2	11-110462	JP			1997-10-01				
	3	94/02140	wo			2000-05-11	Yositomi Pharamce Ind. Ltd.	eutical		

				Applic	ation Number		10036129		
			a. aa	Filing	Date		2001-12-26		
			CLOSURE	First N	lamed Inventor	Tan	eja, Rajneesh		
			PPLICANT	Art Un	nit		1615		
( Not for	subm	ission undei	r 37 CFR 1.99)	Exami	iner Name	Hun	nera N. Sheikh		
				Attorn	ey Docket Numb	er	065478-0298		
			·						
-									T
	4	97/25030	wo		1997-07-	17	Astra Aktiebolag		
If you wis	h to a	dd additional	Foreign Patent Do	cument	citation information	on ple	ease click the Add button		
			NON	I-PATEN	NT LITERATURE	DOC	CUMENTS		-
Examiner	Cite						he article (when appropria		
Initials*	No		azine, journal, seria ity and/or country v		ate, pages(s), volume-issu	ie number(s),	<b>T</b> 5		
		publicher, o	ny anaron obanny						
	1							•	
	'								-
If vou wis	h to a	dd additional	non-patent literatu	re docur	ment citation info	matic	on please click the Add but	tton	
. ,					AMINER SIGNA				
Examine	Signa	ature /	lumera Sheikh/				Date Considered	04/14/2008	
			ace considered wh	ether or	not citation is in	confo	ermance with MPEP 609.	Draw line through a	

Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if

English language translation is attached.

EFS Web 2.0.1

				Applic	ation N	umber		10036129			
				Filing	Date			2001-12-26			
		ION DISCLOSU		First N	lamed I	nventor	Tane	ja, Rajneesh			
		NT BY APPLICA		Art Un	it			1615			
( Not for s	"YEN	oder 37 CFR 1	.99)	Exami	Examiner Name Hur			era N. Sheikh			
(	חבר	0.3 2007		Attorno	ey Docl	cet Numb	er	065478-0298			
12	<u> </u>	U-3 2007	100	1							
- 19			, ,			-					
Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publica Date	tion	Name of of cited D		itee or Applicant ent	Relev	es,Columns,Lines where vant Passages or Relev res Appear	
į	1	20020051814	i i	2002-05	5-02	Chen					
	2	20020051814		2002-05-02		Chen					
	3	20020192299		2002-12-19		Taneja et al.					
	4	20020045646		2002-04-18		Phillips					
If you wisl	h to ac	lld additional U.S. Publi	shed Ap	 plication	ication citation information please click the Add button.					on.	
				FOREIC	N PAT	ENT DOC	UME	NTS			
	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>		Kind Code <sup>4</sup>	Publication Date	on	Name of Patented Applicant of cited Document		Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	l I
	1	85/03443	WO			1985-08-1	5	Sunshine et al.			
	2	93/12517	wo			1993-06-2	24	Fujushita et al.			
	3	95/32957	wo	WO		1995-12-0	)7	Von Unge			
	4	96/01623	wo			1996-01-2	25	Bergstrand et al.			

Application Number		10036129				
Filing Date		2001-12-26				
First Named Inventor	Tane	ja, Rajneesh				
Art Unit		1615				
Examiner Name	Hum	era N. Sheikh				
Attorney Docket Numb	er	065478-0298				

5	96/01625	wo	1996-01-25	Bergstrand et al.	
6	96/07421	wo	1996-03-14	Satoh	
7	96/22780	wo	1996-08-01	Lichtenberger et al.	
8	96/24375	wo .	1996-08-15	Depui et al.	
9	97/25064	wo	1997-07-17	Depui et al.	
10	97/25066	wo	1997-07-17	Depui et al.	
11	98/11879	wo	1998-03-26	Shell et al.	
12	98/13073	wo	1998-04-02	Lichtenberger et al.	
13	98/50033	wo	1998-11-12	Lundy et al.	
14	99/01000	wo	1999-01-07	Jokinen	
15	99/12524	wo	1999-03-18	Skinhoh et al.	

Application Number		10036129				
Filing Date		2001-12-26				
First Named Inventor	Tane	eja, Rajneesh				
Art Unit		1615				
Examiner Name	Hume	era N. Sheikh				
Attorney Docket Numb	er	065478-0298				

16	99/36060	wo	1999-07-22	Wilson et al.	
17	99/39700	wo	1999-08-12	Esposito et al.	
18	99/59612	wo	1999-11-25	Gevas et al.	
19	99/66919	wo	1999-12-29	Ohannesian et al.	
20	00/16750	wo	2000-03-30	Pettersson et al.	
21	00/27366	wo	2000-05-18	Bergstrand et al.	
22	00/50007	wo	2000-08-31	Patel et al.	
23	00/50037	wo	2000-08-31	Garvey et al.	
24	00/51583	wo	2000-09-08	Rubin et al.	
25	00/69438	wo	2000-11-23	Rumsey et al.	
26	00/71122	wo	2000-11-30	Malcolm	

Application Number		10036129			
Filing Date		2001-12-26			
First Named Inventor	Tane	ija, Rajneesh			
Art Unit	••••	1615			
Examiner Name	Hum	era N. Sheikh			
Attorney Docket Numb	er	065478-0298	,		

27	00/72838	wo	2000-12-07	Eek et al.	
28	01/03707	wo	2000-12-14	Mandel et al.	
29	01/13897	wo	2001-01-18	Wilson et al.	
30	01/16750	wo	2001-03-08	West et al.	
31	01/19330	wo	2001-03-22	DeBony et al.	
32	01/37808	wo	2001-05-31	Patel et al.	
33	4432262	DE	1995-07-20	Denecke	
34	0426479	EP	1994-02-16	Goldman et al.	
35	2105193	GB	1983-03-23	Marriott et al.	
36	2105588	GB	1983-03-30	Brittain et al.	
37	2120938	GB	1983-12-14	Ezer et al.	

Application Number		10036129				
Filing Date		2001-12-26				
First Named Inventor	Tanej	eja, Rajneesh				
Art Unit		1615				
Examiner Name	Hume	era N. Sheikh				
Attorney Docket Numb	er	065478-0298				

38	P2000-26296	JP			
39	00/51584	wo	2000-09-08	Rubin et al.	
40	94/25070	wo	1994-11-10	Astra Aktiebolag	
41	00/74654	· WO	2000-05-31	Byk Gulden	
42	02/45692	wo	2001-05-12	Byk Gulden	
43	02/22108	wo	2002-03-21	Chih Ming Chen	
44	19925710	DE	2000-12-14	Gulden et al.	
45	0547000	EP	1993-06-16		
46	01/51050	wo	2001-07-19	Univ. of Missouri	
47	747293	GB	1956-04-01	Abbott Labs	
48	0264259	EP	1988-04-01	Kouchiwa et al.	

			Applic	ation N	umber		10036129			
				Filing	Filing Date			2001-12-26		
		ION DISCLOSU		First N	lamed I	nventor	Tane	eja, Rajneesh		
	_	SSION APPLICA SSION AND RESERVED TO STATE OF THE STATE OF		Art Ur	Art Unit			1615		
` /		. <b>3</b> \	.99)	Exam	iner Naı	ne	Hum	era N. Sheikh		
1	DEC 0.3 5007			Attorn	ey Docl	ket Numb	er	065478-0298		
Remarks to the second s										
<u> </u>	TO THE	10001			<u> </u>			\		
	49	745493	GB			2007-10-	18	MacLeans Ltd.		
	50	2358136	GB			2001-07-	18	DeMontfort Univ.		
If you wish	n to ac	ld additional Foreign P	atent Do	cument	citation	informatio	n ple	ase click the Add buttor	1	
			NON	-PATEI	NT LITE	RATURE	DOC	UMENTS		
Examiner Initials*	Cite No		nal, seria	al, symp	osium,	catalog, e		e article (when appropr te, pages(s), volume-is		<b>T</b> 5
	1	File history of EP Patent Application No: 0426479B1 including the following: European patent application as filed, European search report of February 22, 1991, First Office Action of August 10, 1992 and applicant's reply of December 3, 1992, Communication under Rule 51(4) EPC of February 17, 1993, Applicant's letter of July 30, 1993, Decision to grant a European patent pursuant to Article 97(2) EPC of January 6, 1994 including the non-patent references cited, Communication of notices of opposition (Rule 57(1) EPC) of December 22, 1994, Communication of								
	2	Search Results for NSA	IDS in Co	ombinatio	on with P	roton Pum	o Inhib	itors-performed in 2001		
:	3	Search Results for Prote	on Pump	Inhibitors	s and NS	SAIDS co-a	dminis	tered - performed in 2001		
	WILSON INGALILL ET AL.: "Management of gastroduodenal ulcers and gastrointestinal symptoms associated with nonsteroidal anti-inflammatory drug therapy: A summary of four comparative trials with omeprazole, ranitidine, misoprostol and placebo" Current Therapeutic Research, December, 2001, pp. 835-850, Vol. 62, No. 12									
	5	ROTE LISTE SERVICE: "Rote Liste 2000," 2000, Rote Liste Service, GmbH, Frankfurt, DE A.M. XP002222579								
	6	ROTE LISTE SERVICE A.M. XP002222580	: "Rote L	iste 2000	0," 2000,	Rote Liste	Servic	ce, GmbH, Frankfurt, DE		
	7	SHARMA, V.K. ET AL., as Intact Capsules or as	SHARMA, V.K. ET AL., "Oral pharmacokinetics of Omeprazole and Lansoprazole After Single and Repeated Doses as Intact Capsules or as Suspensions in Bicarbonate," Aliment. Pharmacol. Ther., 2000, pp. 887-892, Vol. 14, No. 7							

			Application Number		10036129			
				Filing Date		2001-12-26		
			DISCLOSURE	First Named Inventor	Tane	eja, Rajneesh		
( Not for submission under 37 CFR 1.99)		Art Unit		1615				
		Examiner Name	Examiner Name Humera N. Sheikh					
				Attorney Docket Numb	er	065478-0298		
	SHARMA, V.K. ET AL., "Simplified Lansoprazole Suspension - A Liquid Formulation of Lansoprazole Effectively Suppresses Intragastric Acidity When Administered Through a Gastrostomy" Am. J. Gastroenterology, August 1999, pp. 1813-1817, Vol. 94, No. 7							
	9		RMA, V.K., "Comparison of 2 prazole," Am. J. Health Syst				insoprazole and	
If you wis	h to ac	d add	ditional non-patent literatu	re document citation info	matio	n please click the Add b	outton	
			,	EXAMINER SIGNA	TURE			
Examiner	Signa	ture	/Humera Sheikh/			Date Considered	04/14/2008	
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								
Standard S	<sup>1</sup> See Kind Codes of USPTO Patent Documents at <a href="https://www.USPTO.GOV">www.USPTO.GOV</a> or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.							

	Application Number		10036129	
	Filing Date		2001-12-26	
STATEMENT BY APPLICANT (Not for supplied on under 37 CFR 1.99)	First Named Inventor	Tane	neja, Rajneesh	
	Art Unit		1615	
	Examiner Name	Hume	era N. Sheikh	
DEC 2 2 2007	Attorney Docket Numb	er	065478-0298	
DEC 0 3 2007	<del></del>			

#### **CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

None

#### SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	Munal Masanen Sa	Date (YYYY-MM-DD)	2007-11-27
Name/Print	1 '(1)	Registration Number	46,720
	J		

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 



### **Privacy Act Statement**

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

- 1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.
- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
  - 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.